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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,124	DYJACH ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6-30-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1–28 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

2. Additionally, in response to Applicant's request for a reference to support the assertion of things "known to one of skill in the art," Examiner provides Levine, U.S. Patent 6,430,441 and Jensen, U.S. Patent 6, 941,332 as prior art that supports the teaching of the use of a first-in-first-out buffer which is well known to be used by one of ordinary skill in the art.

Claim Rejections - 35 USC § 102/103

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 4, 5, 6, 11, 12, 13, 15, 18, 19, 20, 25, 26 and 27 are rejected under 35 U.S.C. 102(e) as anticipated by Oung et al., U.S. Patent 7,079,888 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Oung et al., U.S. Patent 7,079,888.

7. Regarding claims 1, 4, 5, 6, 11, 12, 13, 15, 18, 19, 20, 25, 26 and 27, Oung et al. disclose sensing electrical activity in a cardiac chamber (e.g., Figure 1, element 101, EKG source) and generating a chamber sense signal (e.g., column 5, lines 22–24, where it is the Examiner's position that "produce a pulse train" represents generating a chamber sense signal; lines 55–67); measuring time intervals (e.g., column 5, lines 17–19 and 24–28); filtering BB intervals (e.g., column 5, lines 31–32 and 41–42; column 14, line 10); and, computing heart rate variability metrics (e.g., column 6, lines 16–48; column 8, lines 1–33). It is noted that it is unclear if the implantable medical device is being positively recited; therefore, Examiner used the external device of Oung et al. as cited above as pertinent prior art that discloses the claimed limitations as set forth in the present invention.

8. In the alternative, regarding claim 1, Oung et al. state in column 11, lines 19–20 that the device can be applied in various environments, but not explicitly in an IMD. However, it is well

known in the art to use IMD's to maintain safe, accurate and optimum cardiac function and for the IMD to be operated remotely to ensure reliable, precise and safe cardiac therapy on demand. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Oung et al. to include an IMD to maintain safe, accurate and optimum cardiac function and for the IMD to be operated remotely to ensure reliable, precise and safe cardiac therapy on demand.

9. Claims 1–8, 10–22 and 24–28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, U.S. Patent 6,865,414 and in view of Oung et al., U.S. Patent 7,079,888.

10. Regarding claims 1 and 15, Levine discloses sensing electrical activity in a cardiac chamber and generating a chamber sense signal (e.g., column 5, lines 19–20; column 6, lines 53–59); measuring time intervals (e.g., Figs. 3–5; column 11, lines 7–9; column 17, lines 14–16); filtering BB intervals (e.g., column 12, line 56–column 13, line 5; column 13, line 64–column 14, lines 1–4 and lines 11–18; column 17, lines 9–12). Levine does not disclose computing a heart rate variability metric. However, Oung et al. disclose computing a heart rate variability metric (e.g., column 6, lines 16–48; column 8, lines 1–33) to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions and provide a system that is less sensitive to errors that result during the monitoring time period. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine to include computing a heart rate variability metric, as taught by Oung et al. to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating

personnel in diagnosing and treating various cardiac conditions and provide a system that is less sensitive to errors that result during the monitoring time period.

11. With respect to claims 2–6, 14, 16–20 and 28, Levine discloses a statistic is a median value (claims 2 and 16), and a weighted average (claims 3 and 17) of a plurality of preceding BB intervals (e.g., Fig. 5; column 12, lines 42–64); chamber senses are ventricular senses (e.g., Figs. 2–3 and 7; column 5, line 27; column 10, lines 43–46; column 15, lines 8–13) and BB intervals are RR intervals (claims 4 and 18) (e.g., Figs. 3–5; column 8, lines 7–13; column 11, lines 33–36); a specified threshold value is a specified number (claims 5 and 19) (e.g., Fig. 3) and a specified percentage of a computed statistic (claims 6 and 20) (e.g., Fig. 4; column 11–column 12, lines 1–10); maintaining a count of the number of detected ectopic beats (claims 14 and 28) (e.g., column 1, lines 17–19).

12. Regarding claims 7, 8, 21 and 22, Levine discloses evaluating a present BB interval (e.g., Figs. 3–7) and excluding a present BB interval as an ectopic interval (claims 7 and 21) and removing the oldest interval and storing a present BB interval (claims 8 and 22) (e.g., Figs. 3–7; columns 11–16, lines 1–16). However, Levine does not disclose expressly the claimed limitations of a first-in-first-out **buffer**, where a buffer contains a maximum number N of preceding BB intervals (claims 7 and 21) and updating a **buffer** after each BB interval is evaluated and updating a **buffer** by removing the oldest interval and storing a present BB interval therein if a present BB interval was not excluded as ectopic (claims 8 and 22) [NOTE: Regarding what Levine does not disclose, the emphasis is on the buffer]. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the microcontroller and its associated circuitry (which perform the

limitations of the buffer in the claimed invention) as taught by Levine, to have a first-in-first-out buffer to perform the claimed limitations of the invention as described herein above, because Applicant has not disclosed that a first-in-first-out buffer and its uses thereof provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the microcontroller and its associated circuitry as taught by Levine, because it provides a history record of ectopic events, distinguished by sensing thresholds and timing intervals, giving a valuable diagnostic tool to the physician in optimizing rhythm management therapy.

Therefore, it would have been an obvious matter of engineering design choice to modify the microcontroller and its associated circuitry to obtain the invention as specified in the claim(s).

13. With respect to claims 11–13 and 25–27, Levine discloses the essential features of the claimed invention except for a heart rate variability metric is a parameter computed by time-domain filtering (claims 11 and 25), frequency domain analysis (claims 12 and 26) and a statistical surrogate of a frequency component (claims 13 and 27). However, Oung et al. disclose a heart rate variability metric is a parameter computed by time-domain filtering, frequency domain analysis and a statistical surrogate of a frequency component (e.g., column 6, lines 16–48; column 8, lines 1–33) to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Levine to include a heart rate variability metric is a parameter computed by time-domain filtering, frequency domain analysis and a statistical surrogate of a

frequency component, as taught by Oung et al. to quickly and accurately obtain heart rate variability metrics to better assist medical personnel in diagnosing and treating various cardiac conditions.

14. Regarding claims 10 and 24, Levine discloses a lowest numerical value and a lowest numerical setting (e.g., column 12, lines 31–37), but not that the number N is three. It would have been obvious to one having ordinary skill in the art at the time the invention was made to include that the number N is three, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). (See MPEP 2144.05).

15. Claims 9 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine and Oung et al. as applied to claims 1 and 15 above, and further in view of Jensen, U.S. Patent 6, 941,332.

16. Levine discloses excluding a present BB interval as ectopic if a present BB interval is above or below specified upper and lower limit values (e.g., Figs. 3–7). Levine and Oung et al. disclose the essential features of the ectopic and BB interval limitations as discussed above but not excluding the present BB interval; computing a median value; excluding the present BB interval; and, updating the buffer by: removing the oldest interval from the buffer and storing the present BB interval therein; and, removing the oldest interval from the buffer. However, Jensen discloses excluding the present BB interval; computing a median value; excluding the present BB interval; and, updating the buffer by: removing the oldest interval from the buffer and storing the present BB interval therein; and, removing the oldest interval from the buffer (e.g., Figs. 3–

18; ABSTRACT; column 4, lines 12–37; column 5, lines 15–53; column 14, lines 29–55) to provide efficient and rapid filtering using computational mechanisms to ensure optimum performance of the implantable medical device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Levine and Oung et al. to include excluding the present BB interval; computing a median value; excluding the present BB interval; and, updating the buffer by: removing the oldest interval from the buffer and storing the present BB interval therein; and, removing the oldest interval from the buffer, as taught by Jensen to provide efficient and rapid filtering using computational mechanisms to ensure optimum performance of the implantable medical device.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this Final Action is set to expire THREE MONTHS from the mailing date of this Action. In the event a first reply is filed within TWO MONTHS of the mailing date of this Final Action and the Advisory Action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the Advisory Action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the Advisory Action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this Final Action.

18. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is (571) 272-7146. The Examiner can normally be reached on 7:30 a.m. - 4:30 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
May 4, 2007
4 May 2007

GEORGE R. EVANISKO
PRIMARY EXAMINER
5/7/7